UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
Four Penn Center – 1600 John F Kennedy Blvd
Philadelphia, Pennsylvania 19103-2852

Report Title:	Clean Air Act Inspection of Sterilization Services of Virginia
Inspection Date(s):	May 16, 2023
Regulatory Program(s):	NESHAP
Company Name:	Sterilization Services of Virginia
Facility Name:	Sterilization Services of Virginia
Facility Location:	5674 Eastport Blvd Richmond, Virginia 23231
Latitude:	37.502778 **Longitude:** -77.355556
County/Parish:	Richmond
AFS/ICIS-Air Number:	5108700159
Permit Number:	51000
NAICS Code:	339112 **SIC:** 3841
Unique Project #:	3E23CA095A

Facility Representatives: **Point of Contact**

Jerry McHenry, Plant Manager ☒
Phone: (804) 236-1652 Email: JMcHenry@sterilization-services.com
Tammie Brenner, QA/RA Manager ☐
Phone: (804) 236-1652 Email: TBrenner@sterilization-services.com
David Connor, General Manager ☐
Phone: (804) 236-1652 Email: DConnor@sterilization-services.com

EPA Inspectors:

Paul Arnold, Environmental Engineer, 3ED21
Phone: 215-814-2194 Email: arnold.paul@epa.gov
Carly Joseph, Environmental Inspector, 3ED21
Phone: 215-814-2127 Email: Joseph.carly@epa.gov

State/Local Inspectors:

Eric Deibel, Air Compliance
Phone: (800) 592-5482 Email: eric.deibel@deq.virginia.gov
Sherry Tostenson, Air Compliance
Phone: (804) 664-2832 Email: Sherry.Tostenson@deq.virginia.gov

EPA Lead Inspector Signature _____ **Paul Arnold** **Date**
1600 John F Kennedy Blvd
Philadelphia, PA 19103-2852
PAUL ARNOLD Digitally signed by PAUL ARNOLD Date: 2023.06.12 07:13:12 -04'00'

Supervisor Signature _____ **Kristen Hall** **Date**
KRISTEN HALL Digitally signed by KRISTEN HALL Date: 2023.06.12 06:07:43 -04'00'

Table of Contents

I. Introduction 3
A. Summary of the Facility 3
B. Inspection Opening Conference 3
II. Site Activity/Process Description 4
III. Observations 5
IV. Records Review 5
V. Closing Conference 6
VI. List of Attachments 7

I. Introduction

The United States Environmental Protection Agency (EPA) conducted a Clean Air Act (CAA) inspection at Sterilization Services of Virginia (SSV or Facility) to verify compliance with applicable State and Federal regulations. The Virginia Department of Environmental Quality (VADEQ) was notified of the inspection on April 27, 2023, via email. On May 10, 2023, EPA notified the Facility of the planned inspection via phone and email. EPA emailed a list of records for review to Jerry McHenry, prior to the inspection (see Attachment 1). These records are listed in the Records Review section of the report.

The inspection included an evaluation of the Facility's processes and its compliance with the CAA. All information included in this report is the result of statements by the Facility representatives, materials shown to the inspectors by the Facility representatives, and/or documents provided by the Facility representatives to the inspectors at the time of, or after, the inspection. In addition, information gathered prior to the inspection from a review of EPA and State records may be included in this report.

A. Summary of the Facility

The Facility is located at 5674 Eastport Boulevard, Richmond, VA 23231. SSV offers ethylene oxide (EtO) sterilization services. SSV has a SIC of 3841 and NAICS of 339112, Surgical and Medical Instruments and Apparatus.

The Facility received Synthetic Minor Operating permit 51000 (SMOP) from VADEQ, issued on November 30, 2022. SSV is classified as a synthetic minor for Volatile Organic Compound (VOC) and Hazardous Air Pollutants (HAPs). SSV's potential emissions of Ethylene Oxide (EtO) are above the HAP major source threshold. The Facility is subject to the following federal regulation:

- 40 CFR Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities (Subpart O)

B. Inspection Opening Conference

At 9:00 AM on May 16, 2023, EPA inspectors arrived at the Facility for a CAA Inspection and conducted a brief opening conference. SSV was represented by Tammie Brenner, Rusty Montgomery, Jerry McHenry, Brian Harris, David Hoover, David Connor and Dean O'Keefe. EPA was represented by Paul Arnold, Carly Joseph and Nicholas Bobbs. Also, Sherry Tostenson, Eric Deibel and Patrick Corbett, of VADEQ, were present. EPA inspectors, Paul Arnold, Carly Joseph and Nicholas Bobbs presented their credentials and explained the purpose of the visit was to conduct a CAA compliance inspection to determine compliance with their permit and any applicable regulations. During the opening conference, both SSV representatives and VADEQ stated that the two entities were actively preparing for the proposed EtO rulemaking of the revised Subpart O. Additionally, EPA informed the facility representatives of

their right to claim any confidential business information (CBI). At that time, Jerry McHenry did not claim any photos or documentation as CBI.

II. Site Activity/Process Description

Most of the sterilization services that SSV performs is for medical products. Products requiring Ethylene Oxide (EtO) sterilization are received in the product unloading area. All products are received via truck. Products are received fully enclosed in cardboard boxes or in other types of enclosed containers. Products are sterilized, with EtO, while remaining inside the enclosed containers.

The sterilization process begins with the products entering one of five preconditioning rooms. To facilitate better sterilization, products are placed in preconditioning rooms, where the products are heated to about 125 degrees Fahrenheit and are humidified to 65 percent humidity. Preconditioning can require anywhere from twelve to twenty-four hours. Heat and steam are provided by the facility's primary, and backup, 60 horsepower Cleaver Brooks Boilers. The boilers are fired only with natural gas. After Preconditioning, the products are moved to one of four sterilization chambers. The sterilization chambers are closed, sealed, and drawn under a vacuum to achieve negative pressure. The sterilization chambers are heated to a range of about 105-130 degrees Fahrenheit and EtO is introduced. The amount of EtO required to complete sterilization is dependent upon the quantity of product that requires sterilization. The amount of EtO needed varies from 60 to 240 pounds. The products remain in the sterilization chambers from 8 to 20 hours. Once sterilization is complete, the air in the chambers is evacuated and drawn into either the Croll-Reynolds Scrubber or the CET Scrubber to control EtO emissions. Sterilization Chambers 1 and 4 are usually vented to the Croll-Reynolds Scrubber and Sterilization Chambers 2 and 3 are usually vented to the CET Scrubber. Once the chamber(s) evacuation is complete, the products are transferred to the seven EtO aeration rooms. The sterilized products are then allowed to off gas, in the aeration rooms, for 24 to 72 hours. When in use, the aeration rooms are under negative pressure. All aeration rooms are vented to a single catalytic oxidizer to control EtO emissions. The catalytic oxidizer is required, by Subpart O, to achieve 99% EtO emission reduction. The catalytic oxidizer is heated to 280 degrees Fahrenheit and is continuously monitored. After aeration has completed, the sterilized products are sent a holding/processed area to be shipped out via truck.

SSV has about 50,000 square feet under roof. SSV is privately held and was operating at about 90 percent of capacity during EPA's site visit. SSV has been operational since 1991. SSV has about 25 employees and operates 24 hours a day, seven days per week.

SSV has no emergency generators.

The opening conference concluded at 10:00 AM.

III. Observations

EPA inspectors were led on a walkthrough of the Facility at 10:10 AM by Tammie Brenner and Jerry McHenry, of SSV. Sherry Tostenson, Eric Deibel and Patrick Corbett, of VADEQ, also were present for the walkthrough. EPA inspectors noted photos would be taken during the Facility walkthrough (Attachment 2).

The walkthrough began at the product receiving area and proceeded to the preconditioning rooms where EPA observed one of the rooms partially loaded with products. EPA proceeded to the hallway that led to the four sterilization rooms. All four sterilization rooms were operating and were observed closed. EPA entered the control room and observed the monitors for the catalytic oxidizer and scrubbers. The catalytic oxidizer was observed operating at 300 degrees Fahrenheit (Photo 4). The scrubbers (Photos 5 & 6) were not observed operating during the walkthrough. EPA walked through the hall that provided entry to the aeration rooms and observed the aeration rooms. EPA observed the sterilization room stack (Photo 1) and the catalytic oxidizer stack (Photo 7). EPA observed products that had been sterilized and were being held until shipping could be arranged in the Processed Area.

The walkthrough concluded at 11:30 AM.

IV. Records Review

The records review began at 1:25 PM. EPA inspectors reviewed documents requested in the May 10, 2023, email to Jerry McHenry (see Attachment 1). Records were provided at the time of the inspection by Jerry McHenry. Below are the records requested and what was provided:

The CR Scrubber, the CET Scrubber and the catalytic oxidizer are all individually required, by permit and by Subpart O, to achieve an EtO control efficiency of at least 99 percent. SSV demonstrates compliance with the 99 percent requirement by performing stack testing. SSV last performed stack testing on all three control devices on January 18, 2023; all three control devices demonstrated at least 99 percent control.

SSV is required, by permit and by Subpart O, to replace the catalyst bed every five years. SSV replaced the catalyst beds on October 17, 2019, and on October 7, 2022. SSV is also required to maintain a minimum temperature of 280 degrees Fahrenheit across the catalyst bed. EPA reviewed temperature logs from January 2019 through December 2022.

SSV is required, by permit, to perform annual inspections of both scrubbers. EPA reviewed annual scrubber inspection records, for both scrubbers, for the years 2019 through 2022.

SSV's EtO usage, and EtO and NO_x emissions, are represented in Table A.

TABLE A						
	SMOP Permit Limit	**2019**	**2020**	**2021**	**2022**	**January-April 2023**
EtO Use (tons)	**300**		210	205	254	88
EtO Emissions (tons)	**10**	1.78	2.15	5.33	5.75	not available
NOx Emissions (tons)	**100**	1.79	2.02	2.14	2.28	0.95

V. Closing Conference

After the records review, EPA inspectors, Tammie Brenner, Rusty Montgomery, Jerry McHenry, Brian Harris, David Hoover, David Connor, Dean O'Keefe, Sherry Tostenson, Eric Deibel and Patrick Corbett had a brief closing conference to ask additional questions and discuss observations. The EPA inspectors noted that the investigation is on-going, and any areas of concern identified in the final report do not necessarily reflect a violation or deviation, rather, they are areas that will require further investigation. EPA also noted that they would issue an inspection report within in 60 days, with a copy to the State. Simultaneously, EPA will perform a detailed review of records and may have additional questions. The inspection concluded at 3:15 PM.

VI. List of Attachments

Attachment 1:	Email correspondence to Jerry McHenry of records requested to review during inspection
Attachment 2:	Photo Log